HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use MIUDELLA® safely and effectively. See full prescribing information for MIUDELLA.

MIUDELLA® (copper intrauterine system)
Initial U.S. Approval: 1984

WARNING: RISK OF COMPLICATIONS DUE TO IMPROPER INSERTION

- **Improper insertion of intrauterine systems, including Miudella, increases the risk of complications *[see Warnings and Precautions (5.1)]*.**
- **Proper training prior to first use of Miudella can minimize the risk of improper Miudella insertion *[see Warnings and Precautions (5.1)]*.**
- **Miudella is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Miudella REMS program to ensure healthcare providers are trained on the proper insertion of Miudella prior to first use *[see Warnings and Precautions (5.2)]*.**

---------- INDICATIONS AND USAGE ----------

Miudella is a copper-containing intrauterine system (IUS) indicated for prevention of pregnancy in females of reproductive potential for up to 3 years.(1)

---------- DOSAGE AND ADMINISTRATION ----------

- Insert a single Miudella at the fundus of the uterine cavity. Miudella must be removed or replaced after 3 years. (2.1)
- Insert Miudella only if you are a trained healthcare provider using clean technique. Follow insertion instructions exactly as described. (2.1)
- See the Full Prescribing Information for recommended timing of insertion, preparation instructions, insertion procedures, postplacement management, and instructions on removing Miudella. (2.2, 2.3, 2.4, 2.5, 2.6)
- Patient can be re-examined as clinically indicated.

---------- DOSAGE FORMS AND STRENGTHS ----------

Intrauterine system: 175 mm^2 exposed copper surface area. Miudella has a nitinol frame with copper sleeves and monofilament polymer retrieval thread, preloaded in a sterile inserter.(3, 16)

---------- CONTRAINDICATIONS ----------

- Pregnancy or suspicion of pregnancy. (4)
- Uterine anomaly that distorts the uterine cavity and would be incompatible with correct IUS placement. (4)
- Acute pelvic inflammatory disease (PID) (4)
- Postpartum endometritis or postabortal endometritis in past 3 months. (4)
- Known or suspected uterine or cervical malignancy (4)
- For use as post-coital contraception (emergency contraception) (4)
- Uterine bleeding of unknown etiology (4)
- Untreated acute cervicitis or vaginitis or other lower genital tract infection (4)
- Conditions associated with increased susceptibility to pelvic infections (4)
- Wilson's disease (4)
- A previously placed IUS that has not been removed (4)
- Hypersensitivity to any component of Miudella including copper, nitinol or any trace elements present in the copper components of Miudella (4)

---------- WARNINGS AND PRECAUTIONS ----------

- Risk of Ectopic Pregnancy: Promptly evaluate females who become pregnant for ectopic pregnancy while using Miudella. (5.3)
- Risks with Intrauterine Pregnancy: Increased risk of spontaneous abortion, septic abortion, premature delivery, sepsis, septic shock, and death if pregnancy occurs. Remove Miudella if pregnancy occurs with Miudella in place. (5.4)
- Sepsis: Group A streptococcal infection has been reported; strict aseptic technique is essential during insertion. (5.5)
- Pelvic Inflammatory Disease (PID): Promptly evaluate patients with complaints of fever or abdominal pain after insertion of Miudella. (5.6)
- Perforation resulting in embedment or translocation: May reduce contraceptive effectiveness and require surgery. Risk is increased if inserted in postpartum and lactating females and may be increased if inserted in females with fixed, retroverted uteri or noninvoluted uteri. (5.7)
- Expulsion: Partial or complete expulsion may occur. Remove a partially expelled Miudella. (5.8)
- Bleeding patterns: May be altered and result in heavier and longer bleeding with spotting. (5.10)
- MRI Safety Information: Patients using Miudella can be safely scanned with MRI only under certain conditions. (5.11)

---------- ADVERSE REACTIONS ----------

Most common adverse reactions (incidence ≥ 5%) are: heavy menstrual bleeding, dysmenorrhea, intermenstrual bleeding, pelvic discomfort, procedural pain, pelvic pain, post procedural hemorrhage, dyspareunia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Organon USA LLC, a subsidiary of Organon & Co., at 1-844-674-3200 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 05/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: RISK OF COMPLICATIONS DUE TO IMPROPER INSERTION
1. INDICATIONS AND USAGE
2. DOSAGE AND ADMINISTRATION
2.1 Important Dosage and Administration Instructions
2.2 Timing of Insertion
2.3 Preparation for Insertion
2.4 Insertion Procedure
2.5 Post-placement Management of Miudella
2.6 Removal of Miudella
3. DOSAGE FORMS AND STRENGTHS
4. CONTRAINDICATIONS
5. WARNINGS AND PRECAUTIONS
5.1 Risk of Complications Due to Improper Insertion
5.2 Miudella REMS
5.3 Risk of Ectopic Pregnancy
5.4 Risks with Intrauterine Pregnancy
5.5 Sepsis
5.6 Pelvic Infection
5.7 Perforation
5.8 Expulsion
5.9 Wilson's Disease
5.10 Bleeding Pattern Alterations
5.11 Magnetic Resonance Imaging (MRI) Safety Information
5.12 Medical Diathermy
6. ADVERSE REACTIONS
6.1 Clinical Trials Experience
8. USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.2 Lactation
8.3 Females and Males of Reproductive Potential
8.4 Pediatric Use
8.5 Geriatric Use
11. DESCRIPTION
11.1 Miudella
11.2 Inserter
12. CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
13. NONCLINICAL TOXICOLOGY
13.1 Carcinogenicity, Mutagenicity, Impairment of Fertility
14. CLINICAL STUDIES
16. HOW SUPPLIED/STORAGE AND HANDLING
17. PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: RISK OF COMPLICATIONS DUE TO IMPROPER INSERTION

- **Improper insertion of intrauterine systems, including Miudella, increases the risk of complications *[see Warnings and Precautions (5.1)]*.**
- **Proper training prior to first use of Miudella can minimize the risk of improper Miudella insertion *[see Warnings and Precautions (5.1)]*.**
- **Miudella is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Miudella REMS program to ensure healthcare providers are trained on the proper insertion of Miudella prior to first use *[see Warnings and Precautions (5.2)]*.**

1 INDICATIONS AND USAGE

Miudella is indicated for prevention of pregnancy in females of reproductive potential for up to 3 years.

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosage and Administration Instructions

- Miudella is supplied sterile in a sealed package with a sterile single use inserter for placement. Do not open the package until required for insertion. Do not use if the seal of the sterile package is broken or appears compromised.
- Before considering use of Miudella, make sure that the patient is an appropriate candidate for Miudella. Exclude pregnancy (consider the possibility of ovulation and conception) prior to use *[see Contraindications (4) and Warnings and Precautions (5)]*.
- Only a healthcare provider should insert Miudella. Healthcare providers should be thoroughly familiar with the product, product educational materials, product insertion instructions, and prescribing information before inserting Miudella.
- The IUS is provided preloaded in the inserter (see Figure A).
- Remove Miudella on or before 3 years from the date of insertion.
- Replace Miudella at the time of removal with a new Miudella if continued contraceptive protection is desired.

Figure A: Miudella Intrauterine System (IUS) Preloaded Inserter

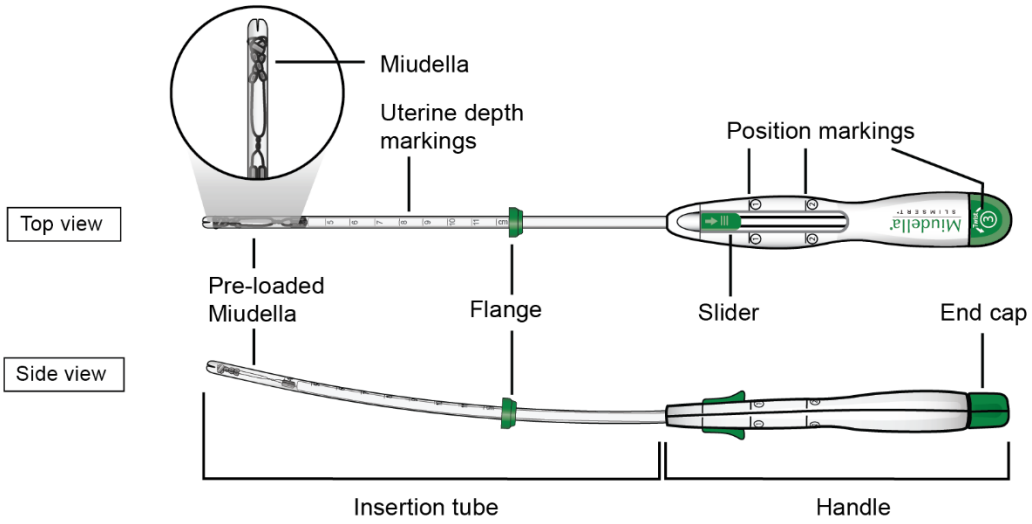
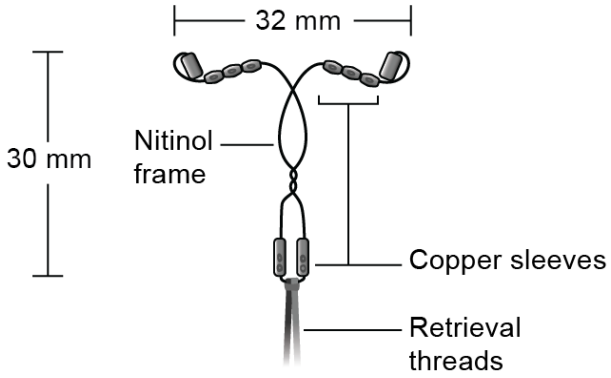


Figure B: Detailed diagram of Miudella



2.2 Timing of Insertion

- Miudella can be inserted at any time during the menstrual cycle. If switching to Miudella from another contraceptive, discontinue the previous method (see Table 1).

Table 1: Recommended Timing of Miudella Insertion

Clinical Scenario	Recommended Timing of Miudella Insertion
1. Start Miudella in females not currently using contraception	At any time during the menstrual cycle.
2. Switch to Miudella from an oral, transdermal, or vaginal form of hormonal contraception or an injectable progestin contraceptive	At any time during the menstrual cycle; discontinue the previous method.
3. Switch to Miudella from a contraceptive implant or other intrauterine system	Same day the implant or IUS is removed (insert at any time during the menstrual cycle).

2.3 Preparation for Insertion

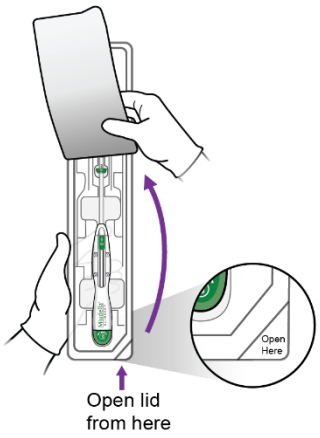
a. Ensure use of clean technique during the procedure.
b. Perform a bimanual exam to establish the size, shape, and position of the uterus and to rule out abnormalities that would preclude safe placement of Miudella.
c. Gently insert a speculum to visualize the cervix.
d. Thoroughly cleanse the cervix with chlorhexidine or povidone-iodine.
e. Apply a sterile tenaculum to the cervix. Apply traction with the tenaculum. Gently advance a sterile uterine sound to the fundus. Note any uterine anomaly and the depth in centimeters.

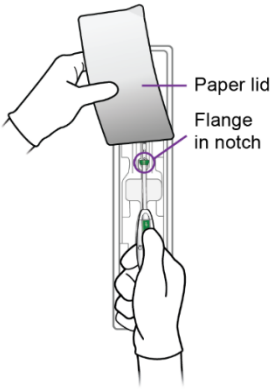
2.4 Insertion Procedure

Step 1 – Open the Sterile Package

a. Remove the sterile packaging containing Miudella from the box.
b. Inspect the packaging to confirm a sterile barrier is maintained. Do not use if the packaging is not intact or there are concerns of compromised sterility.
c. Peel back the paper lid ¾ of the way up the package to expose the inserter handle and flange.

c.



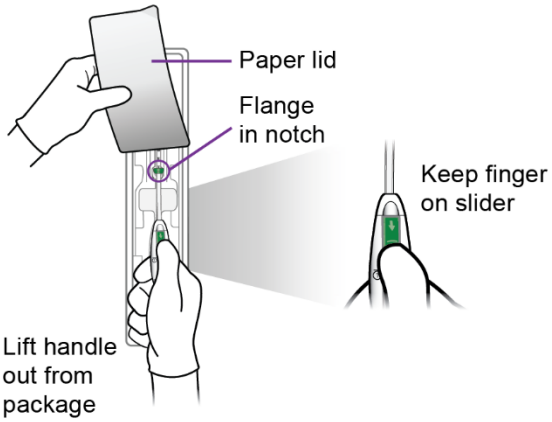


Step 2 – Setting the Flange

a. Grasp the handle while maintaining your thumb or forefinger on the slider to restrict its movement. Gently lift the handle from the package, taking care not to bend or kink the insertion tube. Use the paper lid to hold the flange in the notch of the package, slowly pull the handle back, while keeping the flange in the notch, until the flange is set to the desired depth measured during sounding. Alternately, set the flange with sterile gloves after you have lifted the inserter out of the packaging.

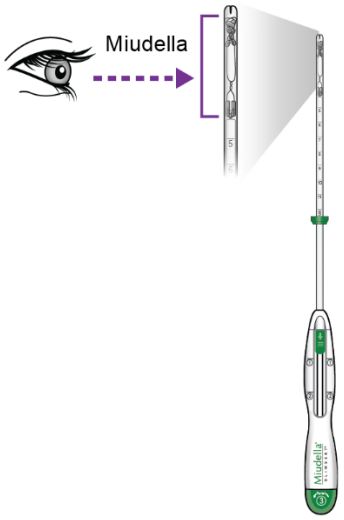
b. After setting the flange, remove the inserter from the package.

a.



c. Inspect the end of the inserter to confirm that Miudella is positioned as shown.

c.

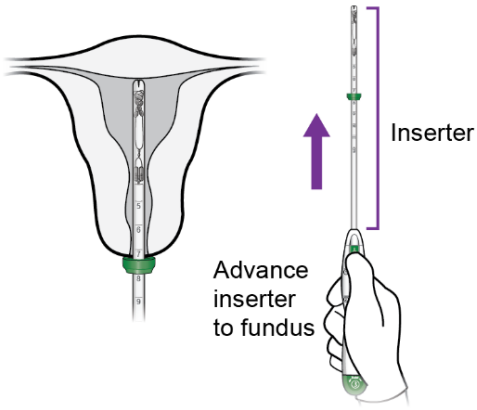


Step 3 – Inserter Placement

a. Continue applying upward pressure with the thumb/forefinger on the slider to avoid early deployment of the IUS. Maintain traction with the tenaculum and gently advance the inserter through the cervical canal. Progress slowly towards the fundus until the flange is at the level of the external cervical os and the tip of the inserter is at the fundus.

- **CAUTION: Do not advance the flange beyond the external os, as this may result in fundal perforation.**
- **NOTE: Do not force the inserter into the external or internal cervical os. If necessary, consider use of an os finder or a small cervical dilator**.

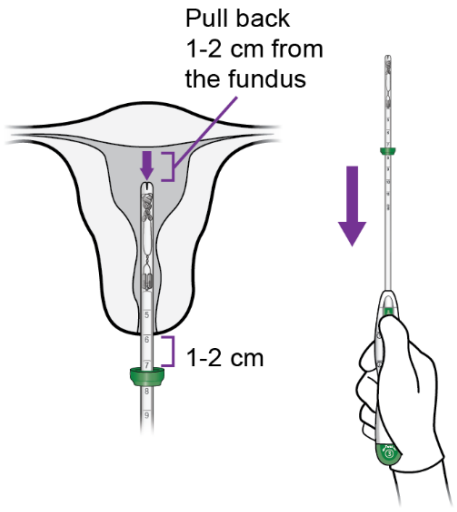
a.



Step 4 -Miudella Placement

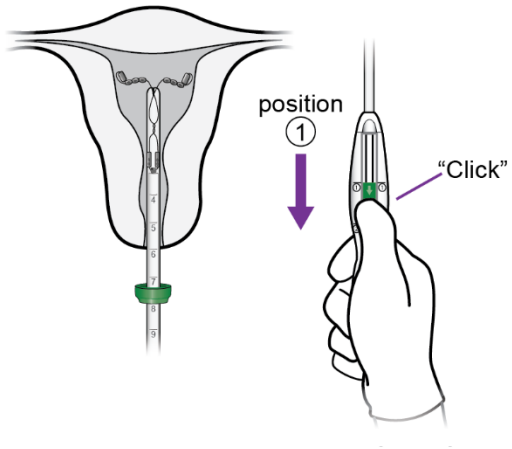
a. Once the flange is at the level of the external os, gently withdraw the inserter back towards you 1-2 cm.

a.



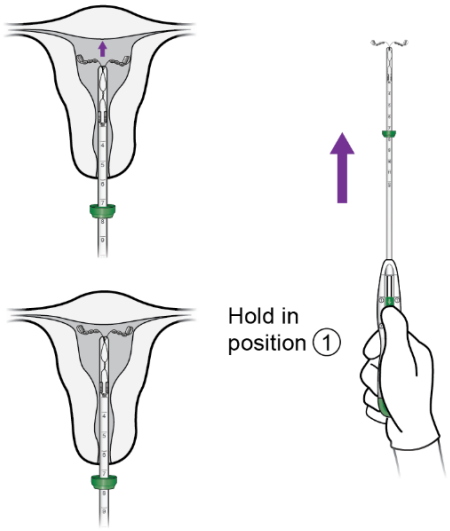
b. With the inserter tip 1-2 cm from the fundus (i.e., with the flange 1-2 cm from the os), move the slider to position ①.

b.



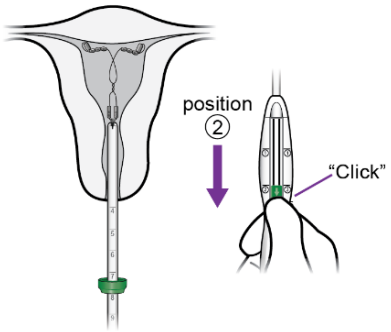
c. Holding the slider securely in position ①, slowly re-advance the inserter until you feel the fundus.

c.



d. With the IUS at the fundus, hold the inserter steady and move the slider to position ②.

d.



e. Release Miudella from the inserter:

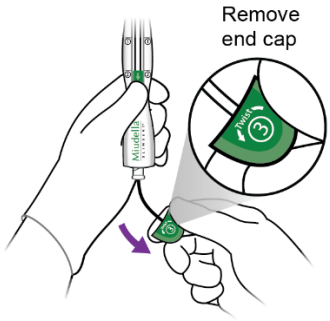
i. Hold the inserter handle steady with one hand and grasp the end cap with the other hand.

ii. While holding the inserter steady with one hand, twist the green end cap (labeled ③) ½ - ¾ turn to the left with the other hand.

iii.

iii. Remove end cap.

One end of the white release thread is attached to the end cap as shown in the diagram and removing the end cap initiates removal of the release thread.

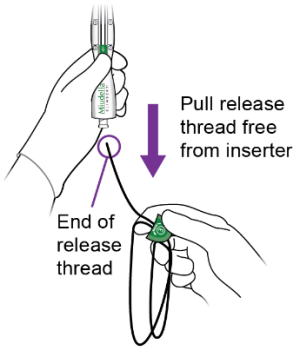


iv.

iv. **Completely** remove the white release thread from the inserter until you see the free end of the thread

Do not cut the white release thread.

The length of the release thread is approximately twice the length of the inserter.



f. Slowly remove the inserter from the cervix and vaginal cavity and properly dispose of the inserter and end cap with release thread.

Step 5 – Confirm the Retrieval Thread Ends

a. Confirm that the blue retrieval thread ends are visible past the external os. The retrieval thread ends are pre-cut to typically allow 3-4 cm of exposed thread in the vaginal cavity without the need for trimming, and hence cutting of excess thread length is generally not required.
b. Should additional trimming of the thread ends be desired, cut the thread ends perpendicular to the thread length, for example, with sterile curved scissors, leaving the desired amount of visible length outside the cervix.
c. Remove the tenaculum and achieve adequate hemostasis.
d. Remove speculum from the vaginal cavity.
e. Miudella placement is now complete.

Important information to consider during and after placement:

- If you suspect that Miudella is not in the correct position, check placement (for example, with transvaginal ultrasound). Remove Miudella if it is not positioned completely within the uterus. A removed Miudella must not be reused.
- If there is clinical concern and/or exceptional pain or bleeding during or after placement, conduct appropriate and timely measures and assessments. For example, ultrasound should be performed to exclude perforation, embedment, or translocation.

2.5 Post-placement Management of Miudella

Following placement:

- Examine the female after her first menses to confirm that Miudella is still in place. You should be able to visualize or feel only the threads. The length of the visible threads may change with time. However, no action is needed unless you suspect partial expulsion, perforation, pregnancy, or breakage.
- If you cannot find the threads in the vagina, check that Miudella is still in the uterus. The threads can retract into the uterus or break, or Miudella can break, perforate the uterus, or be expelled. Gentle probing of the cavity, x-ray, or sonography may be required to locate Miudella.
- Remove Miudella if it has been partially expelled or perforated the uterus *[see Warnings and Precautions (5.7, 5.8)]*.

2.6 Removal of Miudella

Timing of Removal

- Miudella can be removed at any time prior to 3 years after insertion.
- Remove Miudella no later than 3 years after insertion. After removal, a new Miudella can be inserted.
- If the threads are not visible, determine location of Miudella by ultrasound.
- If pregnancy is not desired, and the patient is not having a new IUS or implant placed that day, the removal should be carried out during the first 7 days of the menstrual cycle, provided the woman is experiencing regular menses. If the patient is not having a new IUS or implant placed that day and removal will occur at other times during the cycle or the woman does not experience regular menses, she is at risk of pregnancy: start a new contraceptive method a week prior to removal for these women.

Removal Instructions

1. Use a speculum and visualize the cervix.
2. Remove Miudella with forceps, pulling gently on the exposed threads. The flexible arms of Miudella will fold upwards as it is withdrawn from the uterus. If the threads are not visible, determine location of Miudella by ultrasound.
3. If Miudella is found to be in the uterine cavity on an ultrasound exam, it may be removed using a narrow forceps, such as an alligator forceps. Consider use of local anesthetic for a paracervical block if cervical dilation is required. After removal of Miudella, examine the system to ensure that it is intact.
4. Removal may be associated with some pain and/or bleeding or vasovagal reactions (e.g. syncope, bradycardia, seizures) especially in patients with a predisposition to these conditions.

3 DOSAGE FORMS AND STRENGTHS

Intrauterine system: 175 mm^2 exposed copper surface area. Miudella is a copper-containing IUS that has a flexible nitinol frame with copper sleeves and monofilament polymer retrieval thread, preloaded in a sterile inserter with a tapered rounded tip and packaged in a sealed tray with lid.

4 CONTRAINDICATIONS

The use of Miudella is contraindicated when one or more of the following conditions exist:

- Pregnancy or suspicion of pregnancy *[see Warnings and Precautions (5.4) and Use in Specific Populations (8.1)]*
- Congenital or acquired abnormalities of the uterus, including leiomyomas, resulting in distortion of the uterine cavity
- Acute pelvic inflammatory disease (PID) *[see Warnings and Precautions (5.6)]*
- Postpartum endometritis or postabortal endometritis in the past 3 months. *[see Warnings and Precautions (5.6)]*
- Known or suspected uterine or cervical malignancy

- For use as post-coital contraception (emergency contraception)
- Uterine bleeding of unknown etiology
- Untreated acute cervicitis or vaginitis or other lower genital tract infection
- Conditions associated with increased susceptibility to pelvic infections *[see Warnings and Precautions (5.6)]*
- Wilson's disease [see *Warnings and Precautions (5.9)*]
- A previously placed IUS that has not been removed
- Hypersensitivity to any component of Miudella including to polypropylene, copper, nitinol, an alloy of nickel and titanium, or any of the trace elements present in the copper component of Miudella *[see Adverse Reactions (6) and Description (11)]*. Persons with allergic reactions to these components may suffer an allergic reaction to this intrauterine system. Prior to placement, patients should be counseled on the materials contained in the IUS, as well as potential for allergy/hypersensitivity to these materials.

5 WARNINGS AND PRECAUTIONS

5.1 Risk of Complications Due to Improper Insertion

Improper insertion of intrauterine systems, including Miudella, increases the risk of perforation, infection, undiagnosed abnormal bleeding, pregnancy loss (if pregnancy occurs with IUS in situ), and expulsion.

Proper training prior to first use of Miudella can minimize the risk of improper insertion. Miudella is available only through a restricted program under a REMS *[see Warnings and Precautions (5.2)]*.

5.2 Miudella REMS

Miudella is only available through a restricted program under a REMS called Miudella *REMS Program* to ensure healthcare providers are trained prior to first use *[see Warnings and Precautions (5.1)]*. Notable requirements include the following:

- Healthcare providers must be certified with the program by enrolling and completing training on the proper insertion of Miudella prior to first use *[see Warnings and Precautions (5.2)]*.
- Pharmacies and healthcare settings that dispense Miudella must be certified by enrolling in the REMS and must only dispense Miudella to certified healthcare providers.

Further information is available at miudellarems.com and 1-855-337-0772.

5.3 Risk of Ectopic Pregnancy

Evaluate for possible ectopic pregnancy in any female who becomes pregnant while using Miudella because a pregnancy that occurs with Miudella in place is more likely to be ectopic than a pregnancy in the general population. However, because Miudella prevents most pregnancies, females who use Miudella have a lower risk of an ectopic pregnancy than sexually active females who do not use any contraception.

The incidence of ectopic pregnancy in the clinical trials with Miudella was approximately 0.3%. Ectopic pregnancy may require surgery and may result in loss of fertility.

Patients who use Miudella should be informed about recognizing the signs and symptoms of ectopic pregnancy and promptly reporting them to their healthcare professional, and about the associated risks of ectopic pregnancy (e.g., loss of fertility).

5.4 Risks with Intrauterine Pregnancy

If intrauterine pregnancy occurs with Miudella in place and the thread ends are visible or can be retrieved from the cervical canal, remove Miudella. Leaving it in place may increase the risk of spontaneous abortion and preterm labor. Removal of Miudella may also result in spontaneous abortion. In the event of an intrauterine pregnancy with Miudella, consider the following:

Septic Abortion

In females becoming pregnant with an intrauterine system (IUS), including Miudella in place, septic abortion, with septicemia, septic shock, and death, may occur. Septic abortion typically requires hospitalization and treatment with intravenous antibiotics. Septic abortion may result in spontaneous abortion or a medical indication for pregnancy termination. A hysterectomy may be required if severe infection of the uterus occurs, which will result in permanent infertility.

Continuation of Pregnancy

If a female becomes pregnant with Miudella in place and if Miudella cannot be removed or the female chooses not to have it removed, warn her that failure to remove Miudella increases the risk of miscarriage, sepsis, premature labor, and premature delivery. Prenatal care should include counseling about these risks and that she should report immediately any flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge or leakage of fluid, or any other symptom that suggests complications of the pregnancy.

5.5 Sepsis

Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of IUSs. In some cases, severe pain occurred within hours of insertion followed by sepsis within days. Because death from GAS is more likely if treatment is delayed, it is important to be aware of these rare but serious infections. Aseptic technique during insertion of Miudella is essential to minimize serious infections such as GAS.

5.6 Pelvic Infection

Promptly examine users with complaints of lower abdominal or pelvic pain, odorous discharge, unexplained bleeding, fever, genital lesions or sores. Remove Miudella in cases of recurrent pelvic inflammatory disease or endometritis, or if an acute pelvic infection is severe or does not respond to treatment.

Pelvic Inflammatory Disease (PID)

Miudella is contraindicated in the presence of known or suspected PID or endometritis *[see Contraindications (4)]*. IUSs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion.

Females at increased risk for PID

PID is often associated with a sexually transmitted infection (STI), and Miudella does not protect against STI. The risk of PID is greater for females who have multiple sexual partners, and also for females whose sexual partner(s) have multiple sexual partners. Females who have had PID are at increased risk for a recurrence or re-infection. In particular, ascertain whether the female is at increased risk of infection (for example, leukemia, acquired immune deficiency syndrome [AIDS], intravenous drug abuse).

Subclinical PID

PID may be asymptomatic but still result in tubal damage and its sequelae.

Treatment of PID

Following a diagnosis of PID, or suspected PID, bacteriologic specimens should be obtained and antibiotic therapy should be initiated promptly. Removal of Miudella after initiation of antibiotic therapy is appropriate in cases of recurrent PID or endometritis, or if an acute pelvic infection is severe or does not respond to treatment.

Actinomycosis

Actinomycosis has been associated with IUS use. Symptomatic patients with known actinomycosis infection should have Miudella removed and receive antibiotics. Actinomycetes can be found in the genital tract cultures in healthy patients without IUSs. The significance of actinomyces-like organisms on Pap test in an asymptomatic IUS user is unknown, and so this finding alone does not always require Miudella removal and treatment. When possible, confirm a Pap test diagnosis with cultures.

5.7 Perforation

Partial or total perforation of the uterine wall or cervix may occur during insertions, although the perforation may not be detected until sometime later. Perforation may also occur at any time during IUS use. Perforation that results in embedment or translocation may reduce contraceptive efficacy and result in pregnancy. The incidence of perforation during or following Miudella insertion in clinical trials was 0.1% (2 out of 1904).

A post-marketing safety study conducted in Europe (EURAS IUS) with IUSs, including copper IUSs, demonstrated an increased risk of perforation in postpartum and lactating women. The risk of perforation may be increased if an IUS, such as Miudella, is inserted when the uterus is fixed, retroverted or not completely involuted during the postpartum period.

If perforation is suspected or if known perforation occurs during placement, the IUS should be removed as soon as possible. Surgery may be required. Preoperative imaging followed by laparoscopy or laparotomy may be required to remove the IUS from the peritoneal cavity. Delayed detection or removal of Miudella in cases of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal penetration, intestinal obstruction, abscesses and/or damage to adjacent organs.

5.8 Expulsion

Partial or complete expulsion of Miudella has been reported, resulting in the loss of contraceptive protection. The incidence of expulsion in the clinical trials with Miudella was 3.6% through 3 years of use. Consider further diagnostic imaging, such as x-ray, to confirm expulsion if the IUS is not found in the uterus on ultrasound.

Miudella should be placed no earlier than 4 weeks post-pregnancy to mitigate the risk of expulsion that may be increased when the uterus is not completely involuted at the time of insertion. Remove a partially expelled Miudella and do not attempt to push a partially expelled Miudella into the uterus. If expulsion has occurred, a new Miudella may be inserted when there is reasonable certainty the patient is not pregnant.

5.9 Wilson's Disease

Miudella may exacerbate Wilson's disease, a rare genetic disease affecting copper excretion; therefore, the use of Miudella is contraindicated in females with Wilson's disease *[see Contraindications (4)]*.

5.10 Bleeding Pattern Alterations

Miudella can alter the bleeding pattern and result in heavier and longer menstrual cycles with intermenstrual spotting.
In three clinical trials with Miudella *[see Adverse Reactions (6.1)]*, menstrual changes were the most common medical reason for discontinuation. Discontinuation rates for pain and bleeding combined were highest in the first year of use and diminished thereafter. The percentage of females who discontinued Miudella because of bleeding problems or pain during this study ranged from 8.5% in the first year to 3.2% in Year 3. Females complaining of heavy vaginal bleeding should be evaluated and treated, and may need to discontinue Miudella *[see Adverse Reactions (6.1)]*.

5.11 Magnetic Resonance Imaging (MRI) Safety Information

MRI Safety Information MR **MR Conditional**	The **Miudella Intrauterine Device (IUD)** is MR Conditional. A patient with **Miudella** may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
Nominal Values of Static Magnetic Field (T)	1.5-Tesla or 3.0-Tesla
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., Quadrature-Transmission)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode	Normal Operating Mode
Maximum Whole-Body Averaged SAR	2 W/kg (Normal Operating Mode)
Limits on Scan Duration	2 W/kg whole body average SAR for 60 minutes of continuous RF exposure (a sequence or back to back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. In testing with gradient-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 0.7 cm from the device.

5.12 Medical Diathermy

Medical equipment that contains high levels of Radiofrequency (RF) energy such as diathermy may cause health effects (by heating tissue) in females with a metal-containing IUS including Miudella. Avoid using high medical RF transmitter devices in females with Miudella.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed elsewhere in the labeling:

- Ectopic pregnancy *[see Warnings and Precautions (5.3)]*
- Intrauterine pregnancy *[see Warnings and Precautions (5.4)]*
- Sepsis *[see Warnings and Precautions (5.5)]*
- Pelvic Infection *[see Warnings and Precautions (5.6)]*
- Perforation *[see Warnings and Precautions (5.7)]*
- Expulsion *[see Warnings and Precautions (5.8)]*
- Wilson's Disease *[see Warnings and Precautions (5.9)]*
- Bleeding Pattern Alteration *[see Warnings and Precautions (5.10)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The data described below reflect exposure of 1,904 healthy 17- to 45-year-old women (mean age 27.5 ± 5.72 years) to Miudella. These data come from two multi-center contraceptive trials with a 3-year duration and a single, multi-center comparative bioavailability study with a 3 year duration, all conducted in the United States, enrolling generally healthy, postmenarcheal females to 45 years old. In total 1,904 subjects were exposed to Miudella for one year and 916 completed three years. The data in these trials cover approximately 51,692 cycles of exposure.

The following adverse reactions have been observed in ≥5% of users in clinical trials with Miudella: heavy menstrual bleeding, dysmenorrhea, intermenstrual bleeding, pelvic discomfort, procedural pain, pelvic pain, post procedural hemorrhage, and dyspareunia.

Table 2 shows discontinuation rates from the 3 multi-center clinical studies by adverse reaction and year.

Table 2: Summary of Rates* (No. per 100 Subjects) by Year for Adverse Reactions Causing Discontinuation

	Year		
	1	**2**	**3**
Number of Women at Start of Year	1,904	1,463	1,118
Bleeding/Pain[a]	8.5	5.1	3.2
Expulsion	1.9	1.0	0.9
Other Medical Event[b]	0.2	0.1	0.3

*Rates were calculated by weighting the annual rates by the number of subjects starting each year.

[a] Bleeding/Pain includes the preferred terms (PTs) Abdominal pain, Abdominal pain lower, Post procedural discomfort, Procedural pain, Coital bleeding, Dysmenorrhea, Dyspareunia, Heavy menstrual bleeding, Intermenstrual bleeding, Menometrorrhagia, Pelvic discomfort, Pelvic pain, Polymenorrhea, Uterine hemorrhage, Uterine spasm

[b] Includes PTs embedded device (n=6) and uterine perforation (n=1)

According to the safety analyses of these three studies, it was determined the incidence of expulsion of Miudella did not vary significantly by body mass index (BMI). There was no statistically significant difference in the incidence of expulsion of Miudella in normal weight versus obese females.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Use of Miudella is contraindicated for use in pregnant females because there is no need for pregnancy prevention in a female who is already pregnant and Miudella may cause adverse pregnancy outcomes. If a female becomes pregnant with Miudella in place, there is an increased risk of miscarriage, sepsis, premature labor, and premature delivery *[see Contraindications (4) and Warnings and Precautions (5.3, 5.4)]*. Advise the female of the potential risks if pregnancy occurs with Miudella in place.

Published studies on pregnancy outcomes exposed to copper IUSs report up to 27% miscarriage when the IUS was removed compared to 77% miscarriage when the IUS remained in the uterus. Studies on Miudella and birth defects have not been conducted.

8.2 Lactation

Risk Summary

No difference has been detected in concentration of copper in human milk before and after insertion of copper IUSs, such as Miudella. There is no information on the effect of copper in a breastfed child or the effect on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Miudella and any potential adverse effects on the breastfed child from Miudella.

8.3 Females and Males of Reproductive Potential

Return to Fertility After Discontinuing Miudella

In Study 1 (NCT03633799), return to fertility was investigated in a total of 63 women who desired pregnancy after study discontinuation and provided follow-up information. The probability to conceive within 12 months after removal of Miudella was 74.1% *[see Clinical Studies (14)]*.

8.4 Pediatric Use

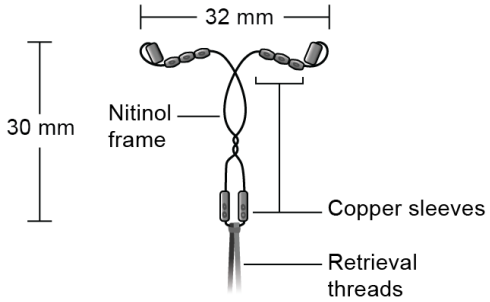
The safety and effectiveness of Miudella have been established in females of reproductive potential. Efficacy is expected to be the same for postmenarcheal females regardless of age. Miudella is not indicated in females before menarche.

8.5 Geriatric Use
Miudella has not been studied in women over 65 years of age and is not indicated in this population.

11 DESCRIPTION

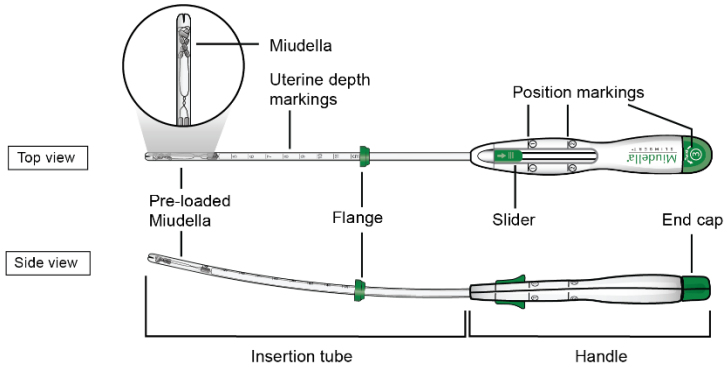
11.1 Miudella
Miudella (copper intrauterine system) contains 99.99% pure copper for use as a contraceptive. Copper (Cu) has a molecular weight of 63.546 g/mol. Miudella consists of ten copper sleeves attached to a flexible nitinol (nickel-titanium alloy) frame measuring 32 mm horizontally and 30 mm vertically, and a polypropylene monofilament retrieval thread tied to the vertical stem. Miudella has a total exposed copper surface area of 175 mm^2 and is provided sterile and preloaded in an inserter.

Figure C: Diagram of Miudella



11.2 Inserter
The inserter device provided with Miudella is a single use, disposable, sterile insertion system (insertion tube with a tapered rounded tip, depth markings and flange, and handle with slider and endcap); preloaded with the IUS for intrauterine administration. Once Miudella has been inserted, the inserter is discarded.

Figure D: Diagram of Inserter



12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
Copper continuously released into the uterine cavity contributes to the contraceptive effectiveness of Miudella. Mechanism(s) by which copper enhances contraceptive efficacy include interference with sperm transport and fertilization of an egg.

12.2 Pharmacodynamics
The exposure-response relationship and time course of pharmacodynamic response for the safety and effectiveness of Miudella have

not been fully characterized.

12.3 Pharmacokinetics

The pharmacokinetics (PK) of copper following insertion of Miudella were investigated in 20 healthy premenopausal female adult subjects. Table 3 shows PK parameters of serum copper with or without baseline-adjustment following 57 days after insertion, and serum copper concentrations during 3 years after insertion.

Table 3: PK parameters and copper concentrations after Miudella insertion

	Parameters	Mean (standard deviation)	
		No adjustment	Baseline-adjusted
PK parameters	$C_{max,\ Day1\text{-}57}$ (ng/mL)	1210 (202)	63.5 (84.1)
	$AUC_{Day1\text{-}57}$ (day×ng/mL)	59700 (8310)	992 (1680)
	C_{Year1} (ng/mL)	965 (197)	7.5 (19.4)
	C_{Year2} (ng/mL)	1020 (168)	25.7 (48.7)
	C_{Year3} (ng/mL)	986 (148)	17.2 (43.0)

C_{max}: peak concentration
C: concentration
AUC: area under the serum concentration-time curve

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenicity, Mutagenicity, Impairment of Fertility

Adequate long-term studies in animals to assess the carcinogenic potential of a copper-containing IUS have not been performed.

A chemical characterization and toxicological risk assessment of the extractables derived from the copper-containing IUS were utilized to address carcinogenicity, mutagenicity and reproductive/developmental toxicity risks. The toxicological risk assessment indicates that the risks of carcinogenicity, mutagenicity and reproductive/developmental toxicity caused by the copper-containing IUS are negligible.

14 CLINICAL STUDIES

The efficacy of Miudella for the prevention of pregnancy in women of reproductive potential for up to 3 years was demonstrated in Study 1 (NCT03633799), a multi-center, single-arm, open-label study conducted in the U.S. Women were excluded if they were less than six weeks postpartum, had a history of previous IUS complications, were known to be HIV positive, or were otherwise at high risk for sexually transmitted infections. There were no exclusions based on BMI.

Study 1 included 1601 generally healthy women aged 17 to 45 years who had Miudella successfully placed. Of these 60% (960/1601) were nulliparous. Successful placement of Miudella with first attempt occurred in 96% of the subjects and 99% with two insertion attempts by healthcare providers who received training on proper insertion prior to first use. The median age was 27 years, the mean weight was 75.3 kg (range 40.6 kg to 170.1 kg); mean BMI was 27.9 kg/m^2 (range 15.8 kg/m^2 to 63.5 kg/m^2); 74% were White, 15% were Black, 5% were Asian, and 6% were Other; 19% were Hispanic.

The primary endpoint for Study 1 was the contraceptive efficacy of Miudella through 3 years of use as measured by the Pearl Index (PI) in women 17 to 35 years of age. The PI was calculated based on 28-day equivalent exposure cycles; evaluable cycles excluded those in which no intercourse occurred, or back-up contraception was used unless a pregnancy occurred in that cycle.
Women enrolled in the study provided 12,493 evaluable 28-day cycle equivalents in the first year and 27,115 evaluable cycles over the three-year treatment period. The PI for Year 1 was based on 9 pregnancies and the cumulative 3-year pregnancy rate was based on 22 pregnancies that occurred after the onset of treatment and within 7 days after Miudella removal or expulsion.

Table 4 shows the calculated annual pregnancy rates and cumulative 3-year pregnancy rate estimated by Pearl Index.

Table 4: Pearl Indices by Year and 3-Year Cumulative Pregnancy Rate[a]

Miudella Clinical Trial	Pearl Index			Cumulative 3-Year Pearl Index
	Year 1	Year 2	Year 3	
Number of Evaluable 28-day Cycles of Exposure	12,493	8,150	6,472	27,115
Pregnancy Rate (95% Confidence Interval)	0.94 (0.43,1.78)	1.60 (0.76, 2.93)	0.60 (0.12, 1.76)	1.05 (0.66, 1.60)

[a] Of the 22 pregnancies, 2 occurred within 7 days of in-clinic removal of Miudella.

Of 54 subjects who desired pregnancy after study discontinuation and provided follow-up information, approximately 74.1% conceived within 12 months after removal of Miudella. The majority of these subjects conceived within 4 months of removal and as early as the first week post-removal, demonstrating the reversibility of Miudella.

16 HOW SUPPLIED/STORAGE AND HANDLING

Miudella (copper intrauterine system) is a copper-containing sterile IUS preloaded in a single use inserter. Each single-use unit is packaged in a sealed tray with lid (NDC-78206-210-01). The IUS is comprised of a nitinol frame with 10 copper sleeves attached to provide a total copper surface area of 175mm^2, and a monofilament polymer retrieval thread tied to the vertical arm.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Before inserting Miudella, counsel patients on the following:
Sexually Transmitted Infections: Advise patients that Miudella does not protect against HIV infection and other sexually transmitted infections.

Ectopic Pregnancy: Advise patients to report pregnancies and be evaluated immediately, as a pregnancy with Miudella in place is more likely to be an ectopic pregnancy, and the risks of ectopic pregnancy include the loss of fertility *[See Warnings and Precautions (5.3)]*.

Intrauterine Pregnancy: Advise the patient to contact her healthcare provider if she thinks she might be pregnant. Inform the patient about the risks of intrauterine pregnancy while using Miudella, including the risks of leaving Miudella in place and the risks of removing Miudella or probing of the uterus. An intrauterine pregnancy with Miudella in place may result in septic abortion, with septicemia, septic shock, and possible death. Septic abortion typically requires hospitalization and treatment with intravenous antibiotics. Septic abortion may result in spontaneous abortion or a medical indication for pregnancy termination. A hysterectomy may be required if severe infection of the uterus occurs, which will result in permanent infertility.

If Miudella cannot be removed in a pregnant patient and remains in the uterus during a pregnancy, there is an increased risk of miscarriage, sepsis, premature labor and premature delivery. Advise patients that a pregnancy must be followed closely and advise patients to report immediately any symptom, such as flu- like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge or leaking of fluid, or any other symptom that suggests complications of the pregnancy. *[See Warnings and Precautions (5.4) and Use in Special Populations (8.1)]*.

Sepsis: Advise the patient that severe infection or sepsis, including Group A streptococcal sepsis (GAS), can occur within the first few days after Miudella is inserted. Instruct her to contact a healthcare provider immediately if she develops severe pain or fever shortly after Miudella is inserted, as untreated sepsis can result in death *[See Warnings and Precautions (5.5)]*.

Pelvic Infection: Advise the patient about the possibility of pelvic infections, including PID, after insertion of Miudella and that these infections can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death. Teach patients to recognize and report to their healthcare provider promptly any symptoms of pelvic infection. These symptoms include development of menstrual disorders (spotting or prolonged or heavy bleeding), unusual vaginal discharge, abdominal or pelvic pain or tenderness, dyspareunia, chills, and fever. *[See Warnings and Precautions (5.6)]*.

Perforation and Expulsion: Advise the patient that the IUS may be expelled from or perforate the uterus and instruct her on how she can check that the thread ends still protrude from the cervix. Inform her that excessive pain or vaginal bleeding during Miudella placement, worsening pain or bleeding after placement, or the inability to feel Miudella strings may occur with Miudella perforation and expulsion. Caution her not to pull on the thread ends and displace Miudella. Inform her that there is no contraceptive protection if Miudella is displaced (for example, expelled or perforated through the uterus). If perforation resulting in displacement occurs, Miudella will have to be located and removed; surgery may be required. Instruct the patient to contact her healthcare provider if she cannot feel the thread ends and to avoid intercourse or use a non-hormonal back-up birth control (such as condoms or spermicide) until the location of Miudella has been confirmed *[See Warnings and Precautions (5.7, 5.8)]*.

Bleeding Pattern Alterations: Advise patients that heavier or longer periods and spotting between periods may occur. Instruct

patients to report continued or severe symptoms to their healthcare provider *[See Warnings and Precautions (5.10)]*.

Magnetic Resonance Imaging (MRI) Safety Information: Inform patients that Miudella can be safely scanned with MRI only under specific conditions. Instruct patients who will have an MRI to tell their healthcare provider that they have Miudella. *[See Warnings and Precautions (5.11)]*.

Medical Diathermy: Instruct patients to tell their healthcare provider that they have Miudella prior to undergoing medical diathermy *[see Warnings and Precautions (5.12)]*.

Clinical Considerations for Use and Removal:

1. Advise patients to contact their healthcare provider if any of the following occur:
   - Pelvic pain or pain during sex
   - Unusual vaginal discharge or genital sores
   - Possible exposure to STIs
   - Very heavy or prolonged vaginal bleeding
   - Missed period
2. Advise patients that they may use tampons or pads while using Miudella.
3. Advise patients that menstrual cups or discs are not recommended for use with Miudella. Use may cause Miudella to become displaced or expelled.

Manufactured for:
Sebela Women's Health Inc.
Roswell, GA 30076
www.miudella.com

PATIENT INFORMATION
Miudella® (mye yoo de' lah)
(intrauterine copper contraceptive)

Miudella® does not protect against human immunodeficiency virus (HIV) or other sexually transmitted infections (STIs).

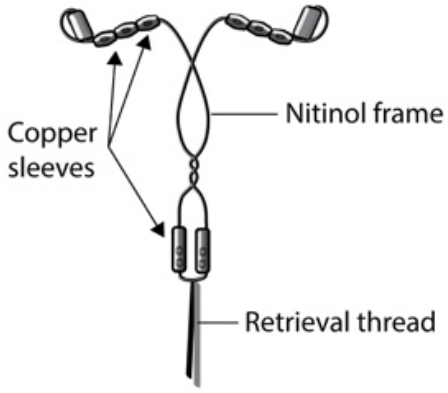
Read this Patient Information carefully before you decide if Miudella is right for you. This information does not take the place of talking with your health care provider (HCP). If you have any questions about Miudella, ask your health care provider. You also should learn about other birth control methods to choose the one that is best for you.

What is Miudella?

- Miudella is a low-dose copper-releasing intrauterine system (IUS) that is placed in your uterus by your health care provider to prevent pregnancy for up to 3 years.
- Miudella can be removed by your health care provider at any time.
- Miudella can be used whether or not you have previously given birth.

Miudella is a small, flexible, hormone-free intrauterine system with copper attached to a flexible wire frame that allows it to fit different uterus shapes and sizes. The wire frame is made of a material used in many medical products.

Miudella has a thin, soft retrieval thread attached to its base. Once Miudella is placed in your uterus, the thread ends extend into the vagina and can be felt. However, unlike a tampon string, the thread ends do not extend outside of your body.



Miudella is small and flexible

What if I need birth control for more than 3 years?

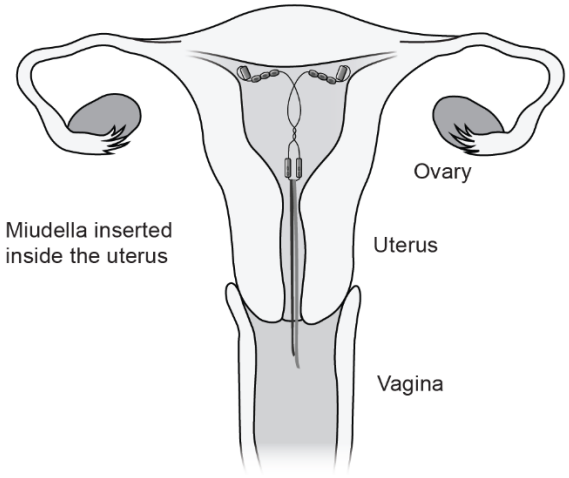
Miudella must be removed at or before 3 years from the date of placement. Your health care provider can place a new Miudella during the same office visit if you choose to continue using Miudella.

What if I want to stop using Miudella?

You can stop using Miudella at any time by asking your health care provider to remove it. Your ability to get pregnant goes back to whatever is normal for you as soon as Miudella is removed; therefore, you should immediately use another birth control method if you do not want to become pregnant. Talk to your health care provider about the best birth control method for you because your new method may need to be started 7 days before Miudella is removed in order to prevent pregnancy.

How does Miudella work?

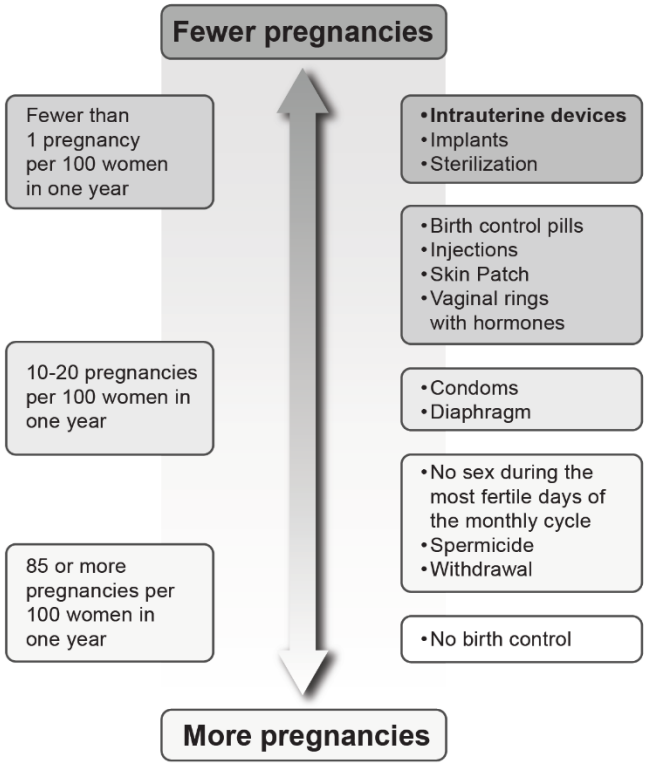
The copper in Miudella works in the uterus by preventing sperm from reaching the egg, or preventing sperm from fertilizing the egg. Miudella does not stop your ovaries from making an egg (ovulating) each month.



How well does Miudella work as a birth control method?

The following chart shows the chance of getting pregnant while using different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.

Miudella, an intrauterine system (IUS), is in the box at the top of the chart.



Who might use Miudella?

You might choose Miudella if you:

- want hormone-free, long-term birth control that provides a low chance of getting pregnant (less than 1 in 100)
- want birth control that can work continuously for up to 3 years
- want birth control that is reversible
- want a birth control method that you do not need to take daily
- are willing to use a birth control method that is placed in your uterus

Do not use Miudella if you:

- are or might be pregnant; Miudella cannot be used as emergency contraception
- have a condition of the uterus that changes the shape of the uterine cavity, such as large fibroid tumors
- currently have a serious pelvic infection called pelvic inflammatory disease (PID)
- have had a serious pelvic infection after pregnancy or an abortion in the past 3 months
- have or suspect you might have cancer of the uterus or cervix
- have unexplained bleeding from your vagina
- have an untreated lower genital infection now in your cervix
- have Wilson's disease (a disorder in how the body handles copper)
- have an intrauterine system in your uterus already
- are allergic to polypropylene, nickel, titanium or copper

Before having Miudella placed, tell your health care provider if you have:

- any of the conditions listed above
- slow heartbeat
- dizziness or history of fainting
- seizures
- recently had a baby or if you are breastfeeding
- have HIV or any other sexually transmitted infection

How is Miudella placed?

Miudella is placed in your uterus during an in-office visit.
First, your health care provider will examine your pelvis to find the exact position of your uterus. Your health care provider will then clean your vagina and cervix with an antiseptic solution and then, measure your uterus. Your health care provider will then slide a slim, tapered plastic tube containing Miudella into your uterus. The tube is removed, leaving Miudella inside your uterus. Two soft thread ends will extend into your vagina. The thread ends are just long enough for you to feel with your fingers when doing a self-check. You may experience pain, bleeding, or dizziness during and after placement. Your health care provider may ask you to lie down until you are feeling better, and to get up slowly. Contact your health care provider if you have prolonged symptoms.

Should I check that Miudella is in place?

Yes, you should check that Miudella is in proper position by feeling the threads. It is a good habit to do this 1 time a month. Your health care provider should teach you how to check that Miudella is in place. First, wash your hands with soap and water. You can check by reaching up to the top of your vagina with clean fingers to feel the 2 thread ends. Do not pull on the thread ends.
If you feel changes in the length of the thread ends, or you cannot feel them, or you can feel any other part of Miudella other than the thread ends, Miudella may not be in the right position and may not prevent pregnancy. Use back-up birth control (such as condoms and spermicide) and ask your health care provider to check that Miudella is still in the right place.

How soon after placement of Miudella should I return to my health care provider?

Call your health care provider if you have any questions or concerns (see "After Miudella has been placed, when should I call my health care provider?"). Otherwise, you should return to your health care provider for a follow-up visit after your first menses after Miudella is placed to make sure that Miudella is in the right position.

Can I use tampons with Miudella?

Yes, tampons may be used with Miudella.

Can I use a menstrual cup or menstrual disc with Miudella?

Menstrual cups and menstrual discs are not recommended for use with Miudella. Menstrual cup and menstrual disc use may cause Miudella to become displaced or come out.

What if I become pregnant while using Miudella?

Call your health care provider right away if you think you may be pregnant. If you get pregnant while using Miudella, you may have an ectopic pregnancy. This means the pregnancy is not in your uterus. Unusual vaginal bleeding or abdominal pain especially with missed periods may be a sign of an ectopic pregnancy.

Ectopic pregnancy is a medical emergency that requires prompt treatment with surgery or medication. Ectopic pregnancy can cause internal bleeding, infertility and even death.

There are also risks if you get pregnant while using Miudella and the pregnancy is in the uterus. Infection, miscarriage, and premature delivery can occur with pregnancies that continue with an intrauterine system. Because of this, your health care provider may try to remove Miudella, even though removing it may cause a miscarriage. If Miudella cannot be removed, talk with your health care provider about the benefits and risks of continuing the pregnancy.

If you continue your pregnancy, see your health care provider regularly. Call your health care provider right away if you get flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection.

It is not known if Miudella can cause long-term effects on the fetus if it stays in place during a pregnancy.

How will Miudella change my periods?

Your period may become heavier and longer. Sometimes the bleeding is heavier than usual at first then often tapers off over the first few months of use. You may also have spotting between periods.

Is it safe to breastfeed while using Miudella?

You may use Miudella when you are breastfeeding. Miudella is not likely to affect the quality or amount of your breast milk or the health of your nursing baby. The risk of Miudella becoming attached to (embedded) or going through the wall of the uterus is increased if Miudella is placed while you are breastfeeding.

Will Miudella interfere with sexual intercourse?

You and your partner should not feel Miudella during intercourse. Miudella is placed in the uterus, not in the vagina. Sometimes your partner may feel the thread ends. If this occurs, or if you or your partner experience pain during sex, talk with your health care provider.

Can I have an MRI with Miudella in place?

Miudella can be safely scanned with magnetic resonance imaging (MRI) under specific conditions. Before you have an MRI, tell your health care provider that you have Miudella, an intrauterine system (IUS), in place.

Can I have a medical procedure using heat therapy with Miudella in place?

Before you have a medical procedure using heat therapy tell your health care provider that you have Miudella in place.

What are the possible side effects of Miudella?

Miudella can cause serious side effects, including:

- **ectopic pregnancy and intrauterine pregnancy risks:** There are risks if you become pregnant while using Miudella (see “What if I become pregnant while using Miudella?”).
- **life-threatening infection:** Life-threatening infection can occur within the first few days after an IUS is placed. Call your health care provider immediately if you develop severe pain or fever shortly after Miudella is placed.
- **pelvic inflammatory disease (PID):** Some IUS users get a serious pelvic infection called pelvic inflammatory disease (PID). PID is usually sexually transmitted. You have a higher chance of getting PID if you or your partner has sex with other partners. PID can cause serious problems such as infertility, ectopic pregnancy, and pelvic pain that does not go away. PID is usually treated with antibiotics. More serious cases of PID may require surgery. A hysterectomy (removal of the uterus) is sometimes needed. In rare cases, infections that start as PID can even cause death.
  Tell your health care provider right away if you have any of these signs of PID: long-lasting or heavy bleeding, unusual vaginal discharge, low abdominal stomach area pain, painful sex, chills or fever.
- **perforation:** Miudella may become attached to (embedded) or go through the wall of the uterus. This is called perforation. Perforation occurs in about 1 out of 1000 insertions. If this occurs, Miudella may no longer prevent pregnancy. If perforation occurs, Miudella may move outside the uterus and can cause internal scarring, infection, or damage to other organs, pain or infertility and you may need surgery to have Miudella removed. Excessive pain or vaginal bleeding during placement of Miudella, pain or bleeding that gets worse after placement, or not being able to feel the threads may happen with perforation. You are not protected from pregnancy if Miudella moves outside the wall of the uterus. The risk of perforation is increased if Miudella is inserted while you are breastfeeding.
- **expulsion:** Miudella may partially or completely come out by itself. This is called expulsion. Expulsion occurs in about 3 out of 100 women. Excessive pain or vaginal bleeding during placement of Miudella, pain or bleeding that gets worse after placement, or not being able to feel the threads may happen with expulsion.
  You may become pregnant if Miudella comes out. If you think that Miudella has come out, use a backup birth control method like condoms and spermicide and call your health care provider.
- **reactions after placement or removal:** Some women have had reactions, such as dizziness (syncope), slowed heart rate (bradycardia), or seizures, immediately after Miudella was placed or removed. These reactions were more common among women who have had these conditions before.

Common side effects of Miudella include:

- **pain or bleeding during and after placement.** You may experience pain, bleeding or dizziness during and after placement. Contact your health care provider if you have prolonged symptoms. Your health care provider will examine you to see if Miudella needs to be removed or replaced.
- **changes in bleeding.** You may have heavier and longer periods with spotting in between. Sometimes the bleeding is heavier than usual at first then often tapers off over the first few months of use. Call your health care provider if the bleeding remains heavier or longer and spotting continues.

Other common side effects include:

- anemia (low red blood cell count)
- pain during sex
- prolonged periods
- vaginal irritation
- backache
- expulsion (complete or partial)
- spotting
- painful periods
- vaginal discharge
- pain and cramping

This is not a complete list of possible side effects with Miudella. For more information, ask your health care provider.
Tell your health care provider about any side effect that bothers you or does not go away.
Call your doctor for medical advice about side effects.
You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
You may also report side effects to the manufacturer through the Organon Service Center at 1-844-674-3200.

After Miudella has been placed, when should I call my health care provider?
Call your health care provider if you have any questions or concerns about Miudella.

Be sure to call if you:

- think you are pregnant
- have pelvic or abdominal pain or pain during sex
- have unusual vaginal discharge or genital sores
- have unexplained fever, flu-like symptoms or chills
- might be exposed to sexually transmitted infections
- are concerned that Miudella may have fallen out (expelled)
- cannot feel Miudella's thread ends
- become HIV positive or your partner becomes HIV positive
- have severe vaginal bleeding that concerns you
- miss a menstrual period
- develop an allergic reaction including itching, swelling, or a rash

General information about the safe and effective use of Miudella. Medicines are sometimes prescribed for conditions that are not mentioned in a Patient Information leaflet. You can ask your health care provider for information about Miudella that is written for health care providers.
For more information, go to www.miudella.com or call the Organon Service Center at 1-844-674-3200.

Miudella® is a registered trademark of Sebela Women's Health Inc. The other brands listed are trademarks of their respective owners.

SEBELA WOMEN'S HEALTH

Manufactured for:

Sebela Women's Health Inc.

Roswell, GA 30076

For more information, call the Organon Service Center at 1-844-674-3200.

This Patient Information has been approved by the U.S. Food and Drug Administration Issued: 05/2026